

PATENT COOPERATION TREATY

corresponding foreign national entry made for notifying overseas patent office

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To: D. YOUNG & CO Attn. Williams, Aylsa 120 Holborn London EC1N 2DY UNITED KINGDOM	ORDER		NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION SOUTHAMPTON 2005 (PCT Rule 44.1)
	DIARY	07/09/05	
	REC'D (LONDON)	08 JUL 2005	
	ANSO		
	ENTRY		
	FOR	1501 AAW	
		Date of mailing (day/month/year)	07/07/2005
Applicant's or agent's file reference P17854WO AAW		FOR FURTHER ACTION See paragraphs 1 and 4 below	
International application No. PCT/GB2004/004783		International filing date (day/month/year) 12/11/2004	
Applicant UCL BIOMEDICA PLC			

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Marilú Masserut

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NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P17854WO AAW	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/GB2004/004783	International filing date (day/month/year) 12/11/2004	(Earliest) Priority Date (day/month/year) 14/11/2003
Applicant UCL BIOMEDICA PLC		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

IMMUNE MODULATOR COMPRISING WHOLE CELL RHODOCOCCUS, GORDONIA, NOCARDIA, DIETZIA, TSUKAMURELLA OR NOCARDIODES BACTERIA

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2004/004783

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 24-25
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 12-25 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 24-25
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
1-23(partially)
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Rhodococcus* for the treatment or prevention of autoimmune diseases or disorders

2. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Gordonia* for the treatment or prevention of autoimmune diseases or disorders

3. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Nocardia* for the treatment or prevention of autoimmune diseases or disorders

4. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Dietzia* for the treatment or prevention of autoimmune diseases or disorders

5. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Tsukamurella* for the treatment or prevention of autoimmune diseases or disorders

6. claims: 1-23 (partially)

use of an immune modulator composition comprising a whole cell bacterium from the genus *Nocardioides* for the treatment or prevention of autoimmune diseases or disorders

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claims 12-25 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.2

Claims Nos.: 24-25

Claims 24-25 do not have additional technical features and therefore, these claims were not searched

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/004783

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K39/39 A61P9/00 A61P37/00 A61P37/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBASE, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/049752 A (INSTITUT PASTEUR; INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MED) 19 June 2003 (2003-06-19) page 4, lines 22-27 page 6, lines 5-8 claims 1,3,5,15,16	1-8, 11-19,23
A	AU 706 122 B2 (UNIVERSITY COLLEGE LONDON) 10 June 1999 (1999-06-10) page 4, lines 3-22; claims 1-3,9-11; examples 2,4 ----- -/--	1-23

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search 13 June 2005	Date of mailing of the international search report 07. 07. 2005
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Noë, V

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB2004/004783

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CONFORTI ANITA ET AL: "Specific and long-lasting suppression of rat adjuvant arthritis by low-dose Mycobacterium butyricum" EUROPEAN JOURNAL OF PHARMACOLOGY, vol. 324, no. 2-3, 1997, pages 241-247, XP002319250 ISSN: 0014-2999 abstract	1,5-7, 12,14, 17-19
A	WO 85/05034 A (UNIVERSITY COLLEGE LONDON; YEDA RESEARCH AND DEVELOPMENT CO. LTD) 21 November 1985 (1985-11-21) abstract page 2, lines 3-9 page 2, lines 15-22 page 5, line 24 - page 6, line 7 claims 1,6,10	1-23
P,X	WO 2004/022093 A (UNIVERSITY COLLEGE LONDON; MCINTYRE, GRAHAM; STANFORD, JOHN, LAWSON; S) 18 March 2004 (2004-03-18) the whole document	1-23

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB2004/004783

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 03049752	A	19-06-2003	AU	2002356387	A1	23-06-2003
			BR	0214902	A	30-11-2004
			CA	2469334	A1	19-06-2003
			EP	1461054	A2	29-09-2004
			WO	03049752	A2	19-06-2003
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AU 706122	B2	10-06-1999	AT	151641	T	15-05-1997
			AT	192046	T	15-05-2000
			AU	675421	B2	06-02-1997
			AU	3637793	A	13-09-1993
			AU	7188796	A	06-02-1997
			BG	99054	A	28-08-1995
			BR	9305946	A	21-10-1997
			CA	2130117	A1	02-09-1993
			CZ	9402023	A3	15-02-1995
			DE	69309915	D1	22-05-1997
			DE	69309915	T2	24-07-1997
			DE	69328503	D1	31-05-2000
			DE	69328503	T2	24-08-2000
			DK	630259	T3	15-09-1997
			DK	763361	T3	07-08-2000
			EP	0630259	A1	28-12-1994
			EP	0763361	A2	19-03-1997
			ES	2104131	T3	01-10-1997
			ES	2145968	T3	16-07-2000
			WO	9316727	A1	02-09-1993
			GR	3024113	T3	31-10-1997
			GR	3033772	T3	31-10-2000
			HU	69941	A2	28-09-1995
			JP	7506093	T	06-07-1995
			KR	275862	B1	15-12-2000
			NO	943082	A	17-10-1994
			NZ	249518	A	27-07-1997
			RO	117833	B	30-08-2002
			RU	2124367	C1	10-01-1999
			SK	99994	A3	10-05-1995
			US	5885588	A	23-03-1999
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WO 8505034	A	21-11-1985	AT	55252	T	15-08-1990
			AU	588809	B2	28-09-1989
			AU	4297685	A	28-11-1985
			DE	3579113	D1	13-09-1990
			EP	0181364	A1	21-05-1986
			WO	8505034	A1	21-11-1985
			JP	7051509	B	05-06-1995
			JP	61502258	T	09-10-1986
			US	4716038	A	29-12-1987
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WO 2004022093	A	18-03-2004	AU	2003263319	A1	29-03-2004
			CA	2497644	A1	18-03-2004
			EP	1534330	A1	01-06-2005
			WO	2004022093	A1	18-03-2004